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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICANT	: Jackowski *et al.*
INVENTION	: **Fibronectin Precursor Biopolymer Markers Indicative Of Alzheimers Disease**
SERIAL NUMBER	: 09/993,289
FILING DATE	: November 23, 2001
EXAMINER	: Cheu, C. Jacob
GROUP ART UNIT	: 1641
OUR FILE NO.	: 2132.092

CERTIFICATE UNDER 37 CFR 1.8(a)
I hereby certify that this correspondence is being deposited with the U.S. Postal Service as First Class mail in an envelope addressed to Commissioner for Patents P.O. Box 1450, Alexandria, VA 22313-1450 on 7-10-03

Susan Dess

Mail Stop: Fee Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION UNDER 37 CFR § 1.132

I, Ferris H. Lander, do hereby declare as follows:

1. I am a registered Patent Agent and am authorized to represent the inventor's and assignee in the application entitled **"Fibronectin Precursor Biopolymer Markers Indicative Of Alzheimers Disease"**, having U.S. Application Serial No. 09/993,289 filed November 23, 2001.

2. In the Office Action mailed on April 7, 2003, claims 1, 2 and 10-28 were rejected under 35 U.S.C. 112, first paragraph because the claimed invention allegedly contains subject matter

which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claims as amended have been limited to specific biopolymer marker peptides (SEQ ID NOS:1-4; the 1356, 1625, 1818 and 1629 dalton markers) useful in methods and kits for diagnosing Alzheimers disease. The method of the invention as recited in claim 39 involves a comparison of the mass spectrum profile of a peptide selected from the group consisting of SEQ ID NO:1, SEQ ID NO:2, SEQ ID NO:3 and SEQ ID NO:4 to mass spectrum profiles of peptides elucidated from a patient sample, wherein recognition of a mass spectrum profile in the patient sample displaying the characteristic profile of the mass spectrum of the peptide selected from the group consisting of SEQ ID NO:1, SEQ ID NO:2, SEQ ID NO:3 and SEQ ID NO:4 indicates that the patient from which the sample was obtained is suffering from Alzheimers disease.

3. In order to provide data which would further support the comparison step involved in the claimed method, I contacted Dr. George Jackowski, Chairman and Chief Science Officer of Syn-x Pharma Inc., and asked to be provided with evidence of the absence of the 1356, 1625, 1818 and 1629 dalton markers in normal human sera (obtained from healthy patients).

4. This declaration (including the attached two figures) is provided in order to show a comparison of the serum profile of individuals having Alzheimers disease to the serum profile of non-diseased individuals, so as to evidence that the markers (the 1356,

1625, 1818 and 1629 dalton peptides) were not present in normal human sera.

The attached figures, obtained from Dr. Jackowski, provide side-by-side profiles (obtained using techniques of mass spectrometry) of normal human sera (top panel of each figure) versus sera from patients having Alzheimers disease (lower panel of each figure). This profile comparison clearly evidences the absence of the 1356, 1625 and 1629 dalton markers in normal human sera.

The undersigned declares that all statements made herein of his own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the Application or any patent issuing thereon.

7/10/2003
Date

Ferris H. Lander
Reg. No. 43,377

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